

REMARKS

Reconsideration of the pending claims is urged in light of the comments below.
New claim 34 is added. No new matter is added.

It is respectfully submitted that the arguments herein place this case in condition for allowance. Reconsideration of the application is urged.

I. The Rejection of Claims 14-23, 25, 26, 29 and 33 under 35 U.S.C. 102(e)

Claims 14-23, 25, 26, 29 and 33 are rejected under 35 U.S.C. 102(e) as being anticipated by Kaasgaard et al., U.S. patent publication no. 2004/0175812 (hereinafter simply referred to as "Kaasgaard"). The Examiner alleges that Kaasgaard discloses adding the polyol or carbohydrates disclosed therein "prior to the recovery step, i.e., during fermentation". Applicants respectfully traverse this rejection.

Applicants respectfully submit that Kaasgaard does not anticipate the present disclosure. As previously explained Claim 14 requires, among other things, adding one or more listed compounds to the culture medium before and/or during fermentation. Applicants have discovered that the specified compounds are suitable for use during fermentation-- thus can be added before and/or during fermentation. Conversely, Kaasgaard is deficient in that it limits disclosure of adding a polyol, and/or a carbohydrate, and/or a derivative thereof, to the culture solution during recovery processing. See, e.g., paragraph 9 of Kaasgaard, which describes added certain compounds to the culture solution prior to, or immediately after, said recovery step. Further, paragraph 12 describes, *inter alia*, avoiding formation of protein crystals/precipitates during recovery processing. Moreover, nowhere does Kaasgaard, including paragraphs 0007-0009, 0051-0057, 0080-0096 describe anything other than adding the compounds prior to a specified recovery step (during recovery processing). The recovery steps of Kaasgaard are specific, and set forth for example in paragraphs [0045], [0046], [0047], [0048], [0049] and [0050]. Nowhere does Kaasgaard describe adding one or more of the compounds to the culture medium before and/or during fermentation, as required by the instant claims.

Inventor Kaasgaard previously explained that one would not infer from the Kaasgaard reference that adding the polyols and/or carbohydrates disclosed in Kaasgaard prior to a recovery step would mean adding the compounds during fermentation. Rather Kaasgaard is limited to adding the polyols and/or carbohydrates prior to the specified recovery steps. See for paragraph 5 of the previously submitted

Kaasgaard declaration. In other words, each of the specified recovery steps occurs after fermentation. Applicants believe that if one were to review the reference as a whole, there is no indication that any of polyols and/or carbohydrates of Kaasgaard should be added before and/or during fermentation. Accordingly, Kaasgaard does not anticipate the claimed invention and reconsideration is urged.

To the extent that the Examiner maintains that the addition of polyols before the recovery step can only be occurring during fermentation, Applicants respectfully disagree. In paragraphs 45-50, Kaasgaard discloses various recovery steps in the recovering processing. In accordance with Kaasgaard, ingredients may be added, e.g., before concentration (recovery processing step 4), or filtration (recovery processing step 5). Accordingly, the Examiner has erred by maintaining that the addition of polyols before the recovery step can only be occurring during fermentation.

Applicants maintain the response of record that anticipation requires enablement. Kaasgaard is not sufficiently enabling to anticipate the present disclosure. Reconsideration is urged.

As Kaasgaard does not describe adding the compounds of claim 14 during fermentation, but rather just before and/or during a specified recovery step, the public was not in possession of the benefits of applying the compounds in a fermentation step.

Accordingly, Kaasgaard is not an enabling reference suitable for use in an anticipation rejection and the reference does not anticipate the claimed invention. Reconsideration is urged.

II. The Rejection of Claims 14-33 under 35 U.S.C. 103(a)

Claims are rejected under 35 U.S.C. 103 as obvious over Kaasgaard. This rejection is respectfully traversed.

As explained previously and above, Applicants maintain that Kaasgaard does not teach adding a polyol to a culture solution during fermentation. Conversely, Kaasgaard describes additions prior to specific recovery steps, all of which occur during recovery processing. Nowhere does Kaasgaard describe adding the specified compounds before or during fermentation. Reconsideration is urged.

Applicants further request reconsideration of the Declaration of inventor Kaasgaard. One of ordinary skill in the art would not consider adding the compounds

specified in claim 14 to the fermentation step based on the Kaasgaard reference. As previously explained in the declaration of Mr. Kaasgaard:

One of skill in the art would not consider adding any of the polyols and/or carbohydrates described in U.S. Publication No. 2004/0175812 during fermentation, as it most often would affect the growth of the microorganisms and the production of the enzyme product negatively. The present invention overcomes this because the polyol and carbohydrate are selected to include only compounds which are not, or only to a low extent, capable of being metabolized by the bacterial fermentation microorganisms.

Accordingly, nothing in the Kaasgaard reference would direct one of ordinary skill in the art to select the specified compounds in claim 14, those compounds which are not, or less likely to be metabolized by the fermentation medium. Kaasgaard does not make the claimed invention obvious. Reconsideration is urged.

III. The Rejection of Claims 14-33 under 35 U.S.C. 103(a)

Claims 14-33 are rejected under 35 U.S.C. 103 as obvious over Schreiber (U.S. 4,016,039) in view of Brothers *et al.* (U.S. 4,673,647) and GB 1001173 and Boyer *et al.* (5,385,837). This rejection is respectfully traversed.

Schreiber is deficient and it does not disclose the process of the present disclosure. Specifically, Schreiber does not teach adding one or more of the recited compounds to the culture medium before and/or during fermentation. Example 1, cited by the Examiner, describes (in past tense) a fermenter broth of bacillus licheniformis "which contains an alkaline protease and which was prepared" . . . was liberated of cell residues and concentrated. Thus, the fermentation was complete and this example describes recovery processing. Similarly, claim 1 cited by the Examiner specifically calls for "the process for recovering an alkaline protease." There is no indication to add PEG during fermentation. Accordingly Schreiber is deficient and fails to disclose each and every element of the claimed invention.

Brothers *et al.* is deficient and does not cure the deficiencies of Schreiber. Specifically, Brothers does not teach adding one or more of the recited compounds to the culture medium before and/or during fermentation. For example, see Column 3, lines 15-40. Here, Brothers explains that in Step 1 the culture is of enzyme secreting microorganism grown in a fermentor. Then, the fermentation products are moved to a drop tank (Step 2). One of ordinary skill in the art would understand that Step 2, begins

the recovery process. In other words, the polyol solvent added in Step 6, does not take place during fermentation.

Further, one of ordinary skill in the art would not necessarily realize that such polyols would be successful during the fermentation step. More specifically, one of skill in the art would not consider adding any of the polyols and/or carbohydrates during fermentation, as it may affect the growth of the microorganisms and the production of the enzyme product negatively. While not wishing to be bound by the present disclosure, or statements, it is believed the present disclose works with the selected compounds because the claimed compounds include only compounds which are not, or only to a low extent, capable of being metabolized by the fermentation microorganisms. For these reasons, *In re Hazra* relating to a composition claims does not apply.

Accordingly, Schreiber and/or Brothers are deficient and fail to provide instruction on applying the claimed compounds before and/or during fermentation.

GB 1001173 is deficient and fails to cure the deficiencies of Schreiber and Brothers. Specifically, GB 1001173 is directed to a process of production of a galactose oxidase from a fungus (*Polyporus circinatus Fr.*). The instant claims relate to bacterium. The reference provides no guidance on bacterial fermentation, thus does not show adding the specified compounds during the requisite fermentation.

Boyer et al. is directed to production of an alkaline *Bacillus* protease, in which suitable carbon sources are indicated as glucose, mannose, fructose, mannitol, maltose, cellobiose, sucrose, dextrin, starch, hydrolyzed starch, molasses, etc.

None of the cited reference teach or suggest, alone or in combination, adding 1,2-propandiol, 1,3-propandiol, ethylene glycol, trehalose, xylitol, arabitol, dulcitol, erythritol, sorbitol and a polyether having an average molecular weight less than 1000 to a bacterial culture medium before and/or during fermentation in accordance with the claimed process.

Applicants note that the Examiner has not provided a sufficient reason or explicit analysis of why the disclosures of the references should be combined. The cited references are devoid of any suggestion to combine the teachings and suggestions of Schreiber, Brothers *et al.*, GB 1001173 and Boyer as advanced by the Examiner, except from using Applicants' disclosure as a template through hindsight reconstruction of Applicants claim. Thus, the Examiner has erroneously retraced the path of the inventor with hindsight --discounting the number of complexities of the alternatives in order to conclude that the specifically claimed method was obvious. This reasoning is always

inappropriate for an obviousness test based on the language of Title 35 that requires the analysis to examine "the subject matter as a whole" to ascertain if it "would have been obvious at the time the invention was made." 35 U.S.C. § 103(a).

Applying a non-rigid TSM analysis, one of ordinary skill in the art would not be motivated by the references to modify the methodology of Schreiber and/or Brothers (or any cited reference alone or in combination) to somehow arrive at Applicants claimed invention. There is no teaching or suggestion to perform the recovery processing steps of the cited references (taken alone or in combination) before and/or during fermentation, and one of skill in the art would not be motivated to do so.

For the foregoing reasons, Applicants submit that the claims overcome this rejection under 35 U.S.C. 103. Applicants respectfully request reconsideration and withdrawal of the rejection.

IV: New claims

New claims 34 is added. The USPTO is authorized to charge the deposit account of Novozymes North America, Inc, 50-1701 should any additional fees be due.

V. Conclusion

In view of the above, it is respectfully submitted that all claims are in condition for allowance. Early action to that end is respectfully requested. The Examiner is hereby invited to contact the undersigned by telephone if there are any questions concerning this amendment or application.

Respectfully submitted,

Date: December 23, 2008

/Michael W. Krenicky Reg # 45411/
Michael W. Krenicky Reg. # 45,411
Novozymes North America, Inc.
500 Fifth Avenue, Suite 1600
New York, NY 10110
(212)840-0097